



MEDICAL DEVICE REVIEW REQUEST

Information provided will be used in evaluating the medical device.

Your Name			Company Name		
Mailing Address			Date		
City	State	ZIP + 4	FAX Number		
Telephone Number			E-Mail Address		
Name of Device			Manufacturer of Device		

Please provide answers on a separate sheet. Number answers to correspond to numbered questions.

1.	a. Why do you believe this device merits consideration and review by the Office of the Medical Director? b. What is the device intended to do?
2.	a. What published, peer-reviewed literature documents the efficacy of this device or the science that underlies it? <i>Please enclose articles or a bibliography.</i> b. Specify which, if any, of the enclosed articles look at the clinical effectiveness of the device and its impact on return to work of the injured workers. c. Are there any sources that would provide useful information? <i>Please enclose or provide a bibliography.</i>
3.	FDA approval: a. Does the device have FDA approval? b. When was the device approved? c. For what indications has the FDA approved the device? d. What approval process was employed (e.g., 510(k), PMA, IDE)? If approved under the 510(k) process, to what device is it substantially equivalent? <i>Please include approval letter and other relevant supporting documents to or from the FDA.</i>
4.	How is this device (1) different from and (2) more efficacious than <u>devices</u> that currently address the medical conditions for which this device has been approved?
5.	How is this device (1) different from and (2) more efficacious than current <u>medical treatment procedures</u> or <u>diagnostic alternatives</u> for this type of injury?
6.	Total cost for the device: a. What is the total cost for the device for which the Department of Labor and Industries will be charged? b. What are the on-going costs associated with the device during the patient's use? c. How does this cost compare with other medical treatment procedures or diagnostic alternatives for this type of injury?
7.	How would this device increase the quality of care the Washington State workers would receive?
8.	How would this device return Washington State workers to work more quickly than existing devices and medical treatment procedures currently do?
9.	Which State workers' compensation programs reimburse for use of this device? <i>Please provide contact names and phone numbers.</i>
10.	Which private insurers reimburse for use of this device? <i>Please provide contact names and phone numbers.</i>
11.	Have any relevant medical organizations (e.g., AMA) expressed an opinion on this device? <i>If so, please provide verification documents and contact names and numbers if possible.</i>
12.	What safety and efficacy issues does use of this device raise?

<i>For Office Use</i>	Date Received:	OMD Personnel
Action	Submitter Advised/Date:	
Comments:		